

REMARKS/ARGUMENTS

Claims 32-50 are active. Support for these claims is found as follows: Claims 32 and 34-37 (Claims 1 and 31), Claim 33 (page 7, line 7), Claim 38 (page 9, line 1), Claim 39 (page 9, line 1, page 8, lines 17 *ff.*), Claim 40 (page 10, line 19), Claim 41 (page 11, line 11), Claim 42 (page 11, lines 2 *ff.*), Claim 43 (Claim 4, page 10, lines 2-6), page 12, line 24) Claim 44 (page 9, lines 7-8), Claim 45 (Claim 6), Claim 46 (Claim 15), Claim 47 (Claim 18), Claim 48 (Claim 19), Claim 49 (Claim 16), and Claim 50 (Claim 20). Accordingly, the Applicants do not believe that any new matter has been introduced. Favorable consideration of these amendments and allowance of this application are now respectfully requested.

Status of Official Action

The coversheet of the Official Action indicates "This action is non-final", however, page 10 indicates it has been made FINAL. The Advisory Action did not indicate that the Applicants prior after-final amendment would be entered upon filing an appeal and indicated that their Declaration would not be entered. Therefore, the Applicants have not had the opportunity to respond to the Examiner's remarks on the Declaration filed after final rejection. Accordingly, the Applicants respectfully submit that any determination of finality is premature and request that this Amendment be entered.

Rejection—35 U.S.C. §103

Claims 1, 2, 6-8, 11-21 and 27-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542. This rejection is moot in view of the cancellation of these claims. It would not apply to the present claims for the reasons previously expressed and in view of the limitation of these claims to specific hydrophilic surface active agents (A).

Yu does not disclose the limitation “wherein the weight ratio of component (B) is more than 11.67 based on 1 of the component (A)”. Nevertheless, the Official Action asserts that it would have been obvious to use this ratio of ingredients on the grounds the routine optimization would have led one with ordinary skill in the art to this value. However, only results-effective variables can be optimized, *In re Antonie*, 195 USPQ 6 (CCPA 1977), MPEP 2144.05 (II). Here, Yu does not disclose that the ratio of (B):(A) is a results effective variable that can be optimized to obtain a particular quality and thus provides no motivation to optimize this ratio, especially outside of the range it discloses. Yu is concerned with selecting an oil having a particular carbon number (page 4, first paragraph) and not with the selection of the particular surface active agent or the particular B:A ratio of the present claims. The Applicants respectfully request that the Examiner specifically point out in the Yu reference where she believes that the ratio of B:A can be optimized to obtain a transparent stable emulsion using the components required by the present claims.

On the other hand, the present invention has the purpose of obtaining a stable emulsion by decreasing the amount of surfactant. Decreasing the amount of surfactant is not disclosed by Yu as a results-effective variable. In the present invention, by limiting the surface tension of the surfactant, an emulsion can be obtained in a system where the amount of surfactant is extremely small, that is at a ratio of oil: surfactant (B:A) of > 11.67: 1.

Even had the Applicants claimed a ratio of (B):(A) less than 11.67: 1, Yu does not disclose that optimizing this ratio would have any effect on the properties of the resulting composition, e.g., by providing a highly transparent product with good stability. A light transmittance at 550 nm of 50% or more is explicitly required by independent Claim 32. The superior properties of the compositions of the present invention are extensively exemplified in the data already of record to which that Applicants refer. Yu does not suggest optimizing the B:A ratio or provide a reasonable expectation of success for obtaining the highly

transparent and stable emulsions obtained by the present inventors by using a small amount of the specific types of surface active agents required by the new claims relative to the oil component and thus cannot render the present claims obvious.

Moreover, Yu provides no motivation for selecting one of the specific types of surface active agents required for (A) as opposed to randomly selecting an agent from a large genus of different compounds many of which have dynamic surface tension values above 57mN/m. The new claims require that (A) be selected from N-stearoylarginine monosodium salt, N-stearoyl-L-glutamic acid monosodium salt, N-stearoyl-N-methyltaurine sodium salt, polyoxyethylene(4) lauryl ether phosphate sodium salt, polyoxyethylen(6) tridecyl ether acetate sodium salt, polyoxyethylene(30) cetyl ether, or stearyltrimethylammonium chloride.

Accordingly, this rejection would not apply to the new claims.

A similar rationale applies to the other prior art rejections based on Yu which are reproduced below.

Rejection—35 U.S.C. §103

Claims 4, 5 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542, in view of Drapier et al., U.S. Patent No. 6,121,228. This rejection is moot in view of the cancellation of these claims.

Rejection—35 U.S.C. §103

Claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542, in view of Ansel et al., Pharm. Dosage Forms and Drug Delivery Systems, 5th edition. This rejection is moot in view of the cancellation of this claim.

Rejection—35 U.S.C. §103

Claims 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542, in view of Gers-Barlag et al., U.S. Patent No. 5,876,702. This rejection is moot in view of the cancellation of this claim.

Rejection—35 U.S.C. §103

Claims 23 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542, in view of Diec et al., U.S. Patent No. 6,468,551. This rejection is moot in view of the cancellation of these claims.

Rejection—35 U.S.C. §103

Claims 24 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542, in view of Brunetta et al., U.S. Patent No. 5,562,911. This rejection is moot in view of the cancellation of these claims.

Rejection—35 U.S.C. §103

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, JP63-126542, in view of Shiojima et al., U.S. Patent No. 6,066,316. This rejection is moot in view of the cancellation of this claim.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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